



Institutional Review Board
For Human Participant Research
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**Institutional Review Board
Student (Other Investigator) Instructions & Information**

Do not begin work until written IRB approval is issued!

Please read these instructions in their entirety. Note that only faculty members can serve as Principal Investigators; students are listed as “Other Investigator.”

Type for Review and Application

You should meet with your Principal Investigator (faculty member) to determine the forms for your project. Depending on the risk involved to participants of your proposed study, your research proposal may qualify for one of three levels of review: Exempt, Expedited, or Full Review. The following steps are designed to assist you in choosing the level of review.

If your project meets all of the following criteria, you should select Exempt Review Requested:

- Research conducted in established or commonly accepted educational settings.
- Research involving the use of educational tests if participants cannot be identified.
- Research involving surveys, interviews, or observations of public behavior that does not deal with sensitive or critical responses. All research using survey or interview procedures is exempt when the respondents are elected, appointed public officials, or candidates for public office.
- The project will not involve participants in high risk groups (See Expedited Application, Item 10).
- Research involving the collection or study of existing data or specimens that are either publicly available, or not individually identifiable.

If your project meets any of the following criteria, you should select Expedited Review.

- Collection of hair, nail clippings, dental plaque and calculus or teeth in a non-disfiguring manner, or secretions.
- Recording of data from participants 18 years of age or older using noninvasive procedures routinely employed in clinical practice.
- Collection of small amounts of blood (550 mL or two samples per week) by venipuncture from healthy, non-pregnant participants, 18 years of age or older and weighing at least 110 pounds.
- Voice recordings made for research purposes such as investigations of speech defects.
- Moderate exercise by healthy volunteers.

- Research on individual or group behavior where the investigator does not manipulate participants' behavior and the research will not involve stress to the participants.
- Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

If your project does not meet the criteria above, you must select Full Review.

Required Documents

All documents should be submitted 1) electronically or 2) signed hard or scanned copy.

Electronic Copies to: irb@ucwv.edu or Hard (paper) copies to: Institutional Review Board, UC-Charleston, Box 9.

If you selected Exempt Review Requested, you must submit the following items:

- Application for Exempt Review (Application and Consent Form)
- Explanation of study for participants (informed consent optional)
- Appendices [eg: surveys, questionnaires, or tests] (conditional)
- Consent for photographic or voice recording (conditional)
- Permission to conduct research at a Non-UC site (conditional)
- Proposal
- Sponsored Research Form (conditional)

Timeline

Assuming that the proposals are complete and that no major revisions are requested, the timeline for processing applications will be as follows:

- Exempt Review: Four weeks
- Expedited Review: Six weeks
- Full Review: Eight weeks

How to Submit Your Proposal

- 1) Begin Early to allow sufficient time for review to be completed before involving participants. Refer to timeline for standard time based on your application type.
- 2) Use current forms found on IRB webpage at: www.ucwv.edu/Academics/Research/Institutional-Review-Board/
- 3) Use all forms/items, as outlined under Required Documents
- 4) Complete all forms in their entirety.
- 5) Verify that you have fully described the method of confidential storage of data.
- 6) Compile your proposal with the appropriate forms and materials.
- 7) Submit an electronic copy of your proposal to the IRB via email to: irb@ucwv.edu
- 8) Print a hard (paper) copy of your application.
- 9) Obtain all required signatures on your hard (paper) copy or Adobe Digital Signature.

- 10) Submit your signed (paper) copy via interoffice mail to: Institutional Review Board, UC-Charleston, Box 9.
- 11) Be Patient. Keep in mind the timeline for your category, while your proposal is “Out for Review.”
- 12) IRB Response will be sent to you in the form of an email letter, stating that:
 - a) Your proposal has been approved; that you may proceed with your research, and listing your IRB number. You will not receive your IRB number prior to the issuance of this letter. (Do not begin any work until you receive this letter.) Or,
 - b) You will be asked to provide additional information, forms, or to alter your proposal in some way. (If you receive this request, it is important that you respond quickly as delays in responding will delay the approval process of your application. Failure to respond will result in your application not being approved.

Follow-up

All correspondence to the IRB about existing protocols must contain your protocol number.

- All studies must be reviewed on an annual basis; unless they are officially closed via the submission of a Closure Report to the UC-IRB. All proposals and related signed consent forms must be placed in the IRB files, where they are housed for at least three years after the completion of your study. Therefore, it is your responsibility to follow-up to ensure that you properly close your file or request a renewal.
- If your project extends beyond the anniversary of your approval, you must submit an Annual Renewal-Progress Report.
- Once you have completed your study or decide to terminate it, you must file a Notice of Closure form to close out your file.
- These forms can be found on the IRB website:
<http://www.ucwv.edu/Academics/Research/Institutional-Review-Board/>

Questions or concerns, please contact Rebecca Linger, IRB Chair, x-4998 or irb@ucwv.edu

Institutional Review Board Frequently Asked Questions

It is our goal to guide you through the IRB process and give you an understanding of the importance of the IRB and our compliance with the process.

What is the purpose of an IRB? The purpose of the IRB is to review projects involving human research to ensure that the subjects are treated humanely and fairly. Failure to comply with federal regulations by not having a functioning IRB or not notifying the IRB of such projects and obtaining approval prior to starting a project could cause UC to lose federal funding. Therefore, it is extremely important that these projects go through the proper approval process and you do not begin any human research until you receive a written approval from the IRB.

When do I need to have a project reviewed by the IRB? Any time you have a project involving collection of data or samples from human subjects or research on human subjects. This includes surveys, unless they are only asking for opinions. (Refer to UC-IRB website for more detailed guidelines.)

Who is the Principal Investigator? This must be a UC faculty member, normally the faculty member assigning the project.

How do I submit an application?

- Meet with your Professor/Instructor to discuss the type of application you need. Review the checklist on our site for more detail. Once you select the type of application, it will list the forms required.
- Complete the application in its entirety, attach any additional forms (surveys, consents, questionnaires, tests, etc.) and sign the application under “Other Investigator.”
- Take the completed application packet to your Professor/Instructor and ask him/her to review it and sign off on it. Then:
 - a) Submit an electronic copy of your proposal to the IRB via email to: irb@ucwv.edu
 - b) Submit your signed (paper) copy via interoffice mail to: Institutional Review Board, UC-Charleston, Box 9.

What happens next? Upon receipt of your application packet, it will be checked for completeness, including all required signatures and all required documents by the IRB coordinator. If it is acceptable, it will be forwarded to IRB members for review. If it is not acceptable, it will be returned to your Principal Investigator for corrections.

Once your application has gone out for review, the Board will review the material. If the reviewers accept your application as is, your application will be forwarded for approval to the IRB Chair. If the reviewers do not accept your application as is, you will be notified to make modifications or clarifications. At that point, your response is required before your application can move forward.

How long does it take to get approval? Assuming that the proposals are complete and that no major revisions are requested, the timeline for processing applications will be as follows: Exempt Review, four weeks; Expedited Review, six weeks; Full Review, eight weeks.

How do I know when my application is approved? Once our application is approved, you will be issued an approval letter with your application number.

How long is my approval valid? Once approved, your approval is valid for one year. If you expect your project to go beyond your one-year anniversary, it is your responsibility to get with your PI and submit a “Renewal/Progress Report” 60 days prior to the expiration.

Other Reports? Once you have completed your project, you must formally close it. You will need to complete a “Closure Report” and have it signed by your PI, then attach a copy of your summary before forwarding to the IRB. If your project requires work beyond the expiration of approval, you will need to complete a “Renewal Application / Progress Report.”